SmartSound

Ultrasound/Electro-Stimulation
Combination Therapy Unit
With Automatic Pulse Sweep
&
Synchronized Ultrasound/Electro-Stimulation

Operating Manual

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FEDERAL LAW RESTRICTS THIS DEVICE TO THE USE BY OR SALE TO (OR ON THE ORDER OF) A PHYSICIAN OR OTHER PRACTITIONER IN THE STATE LICENSED IN WHICH SAID PERSON PRACTICES.

Unpacking and Assembly

The *SmartSound* is shipped as a complete unit in one carton containing the unit and accessories. Upon receipt of the unit, check it thoroughly for shipping damage. If damage is found, save all shipping materials and notify the carrier. A claim must be filed with the carrier, as SoundSkin Corporation is not responsible for shipping damage.

For ultrasound, the only assembly required is attaching the applicator to the unit at the front panel connector labeled "Transducer Output", and connecting the *SmartSound* to a source of AC power.

For stimulator treatment, attach the stimulator output leads and pads.

The unit is wired to run on 115 Volt alternating current (special voltages can be accommodated on request).

CAUTION: All electrical equipment used in medical applications must be properly grounded.

IMPORTANT: The generator and ultrasound applicator are shipped as a unit, calibrated for output power and intensity. The serial numbers for both are as specified below. If any other generator is connected to this applicator, or any other applicator connected to this generator, SoundSkin Corporation does not guarantee the accuracy of the ultrasound output power and intensity calibration.

If interchanging generators and applicators becomes necessary, the unit must be returned to SoundSkin Corporation for recalibration.

Stimulator calibration will not be affected by change of any accessories.

Purchase Date: _____

Generator Serial Number: _____

Applicator Serial Number: _____

USER RESPONSIBILITY

The *SmartSound* is designed to perform as described in this manual when it is operated, maintained, and repaired in accordance with the instructions provided. The *SmartSound* must be checked periodically. Components that are broken, missing, plainly worn, distorted or damaged should be replaced before further use. This product or any of its parts should not be repaired other than in accordance with written instructions provided by SoundSkin or an authorized SoundSkin distributor. The user of the *SmartSound* shall have the sole responsibility for any malfunction, which results from improper use, faulty maintenance and calibration, improper repair, damage, or alteration by any one other than SoundSkin or an authorized SoundSkin representative.

The *SmartSound* is designed to operate directly from power line sources and, therefore, can be dangerous if service precautions are not taken.

CAUTION: Refer servicing to qualified personnel only.

Section 1

GENERAL INFORMATION

Introduction

The *SmartSound* is a dual-purpose combination unit. It features continuous/pulsed ultrasound and a stimulator output. The stimulator output is a high voltage "DynaWave type" current. Therefore, this modality can be used either as an ultrasound unit, as a stimulator only, or for combination treatment.

Treatment parameters are programmable via front panel controls. A digital Output Display indicates either Stimulator output (Volts) or Ultrasound (Power/Intensity), depending on the position of the selector switch. Both outputs incorporate a Zero-Start feature. This means the output is not active unless the respective output control is started from a zero (counter-clockwise) position. An active output is indicated by the respective "Output On" light.

Features

- Modular construction for ease in maintenance
- Front panel controls arranged in functional blocks
- Safety shielded power transformer
- Programmable treatment time
- Treatment time ending audio alert
- Over temperature protected ultrasound applicator
- Feedback control of ultrasound power
- Continuous or pulsed ultrasound
- Accurately calibrated power/intensity readout for ultrasound
- Accurately calibrated stimulator output voltage
- Twin pulses in stimulator output
- Positive or negative selection for active stimulator electrode
- Unique automatic "Pulse Sweep" feature for stimulator output
- Pulsed mode ultrasound synchronized to stimulator output – including automatic sweep

Section 2
SPECIFICATIONS

Physical

Size	7-5/8" high, 17" wide, 13-1/4" deep
Weight	22 pounds
Electrical	115 VAC ±10% 1.2 amps, 50/60 Hz (special voltages available on request)

Ultrasound Generator

Ultrasonic Frequency	2.2 MHz ±10%
Radiated Power	0 to 10 Watts continuous or pulsed, continuously variable. Accuracy in display of power is ±20%.
Radiated Intensity	0 to 2 Watts per cm^2 continuous or pulsed, continuously variable. Accuracy in display of intensity is ±20%.
Pulse Duration	Functional in pulsed mode. Fixed at 5 milliseconds. Accurately displayed to within ±20% at intensity levels above 0.2 W/ cm^2.
Pulse Period	Functional in pulsed mode. Automatically sweeps over the range of 10 to 100 milliseconds in synchronization with stimulator output.
Treatment Time	0 to 99.9 minutes, variable in increments of 0.1 minute (6 seconds). Timer accuracy to within 0.5 minute of the preset duration of emission for settings less than 5 minutes, to within 10% of the preset duration of emission for settings of from 5 minutes to10 minutes, and to within 1 minute of the preset duration of emission for settings greater than 10 minutes.
Temporal Maximum/Average Intensity Ratio Min.	Minimum 2 ±5%, Maximum 20 ±5%.

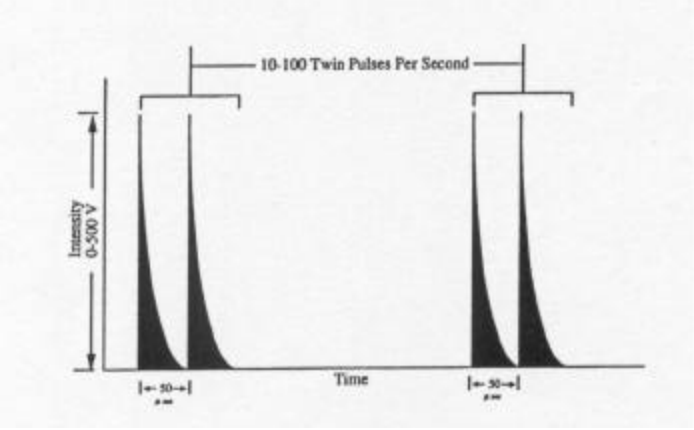
Ultrasound Applicator (Crystal)

Material	Lead zirconate titanate
Frequency (f)	2.2 MHz ±10%
Effective Radiating Area	5 cm^2 ±20%
Type	Collimating
Maximum Beam Nonuniformity Ratio	4.2

SPECIFICATIONS (Continued)

Stimulator Section

Type Output:	High voltage unidirectional pulses
Output Waveform:	Twin peaked pulses, nanosecond rise time, exponential decay, microsecond duration
Output Adjust:	Continuously variable from 0-500 volts
Pulse Rate:	Continuously sweeping from 10- 100 pulses per second, 50 sec. intervals
Interval Spacing:	Fixed at 50 microseconds
Polarity:	Selectable, positive or negative
Electrodes:	2 pads, 4 pads, or ultrasound applicator
Safety Features:	Multiple fail-safe features, zero reset start control

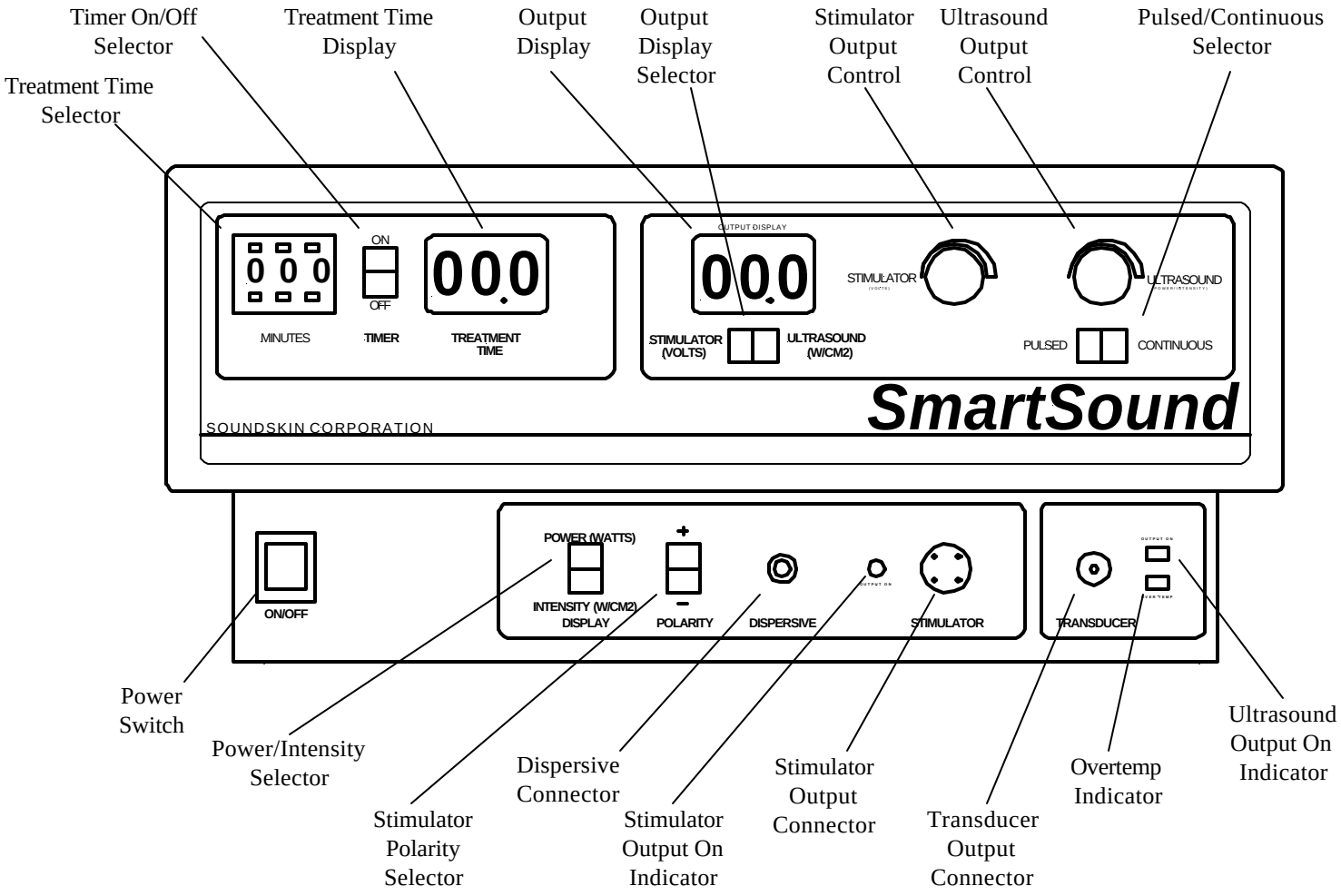


Abbreviations

Name	Where Used	Definitions
S/N	Applicator and Generator	Serial Number
Type Coll	Applicator	Applicator produces a collimating ultrasound beam
ERA	Applicator	Effective Radiating Area
BNR	Applicator	Maximum applicator Beam Nonuniformity Ratio
F = 2.2 MHz	Applicator	Applicator nominal frequency of operation

DO NOT OPERATE THE UNIT WITHOUT A SOUNDHEAD CONNECTED

CONTROLS & DISPLAYS



Section 3

OPERATION CONTROLS/DISPLAYS

Dispersive Connector	This connector accepts the dispersive lead plug.
Output Display	When in "Ultrasound" display mode, the display indicates power or Intensity (in Watts or Watts/ cm^2 respectively). When in "Stimulator" display mode, the display indicates peak volts.
Output Display Selector	Selects whether the display indicates stimulator output (Volts), or ultrasound output (see also “Power/Intensity Selector).
Overtemp Indicator	This indicator will light if the ultrasound transducer heats up due to poor coupling with the patient. The unit will automatically shut off and the transducer must be allowed to cool before resuming treatment.
Power/Intensity Selector	Functional only when the “Output Display Selector” is set to the “Ultrasound” position. It determines whether the Output Display indicates ultrasound “power” in Watts, or ultrasound “intensity” in Watts per square centimeter (W/cm^2).

Power Switch	Activating this rocker switch will turn the unit on and the switch will be illuminated.
Pulsed/ContinuousSelector	This switch selects the operating mode for the ultrasound Output, either continuous or pulsed ultrasonic power.
Stimulator Output Connector	The dispersive electrode must be used for both combination and pad treatment. The pad lead and connection is needed only when treating with the small pads.
Stimulator Output Control	Clockwise rotation of this control increases, and counter-clockwise rotation decreases stimulator output. Must be set to full CCW position initially before output will activate (zero start feature).
Stimulator Output ON Indicator	Whenever the Treatment Timer is “on”, this indicator will be activated. It means that the unit is ready to deliver stimulation by advancing the Stimulator Output Control clockwise. The indicator will show a light that is synchronized to the stimulator output. Brightness of this pulsating light will increase or decrease with the corresponding change in pulse repetition rate. The stimulator light is synchronized to the pulse repetition rate and will appear as a steady light at higher pulse rates.
Stimulator Polarity Selector	This switch determines the polarity of the stimulator output. When the switch is in the “+” position, the stimulator output is positive with respect to the dispersive. When the switch is in the “-“ position, the stimulator output is negative with respect to the dispersive.
Timer On/Off Selector	In order to commence Treatment Time, the timer switch must be depressed "on". This switch may be used at any time to manually turn "off" the Treatment Time and output power.
Transducer Output Connector	This is the output socket for the connection of the ultrasound soundhead (transducer).
Treatment Time Selector and Treatment Time Display	The Treatment Time is selected by the digital selector switch in minutes and tenths of minutes up to a maximum of 99.9 minutes. Upon pressing the “Timer On/Off Selector” switch, the treatment time indicators light up and the timing begins. The timer counts down in 0.1 minute increments and automatically terminates the ultrasound and stimulator output upon reaching 00.0 count.
Ultrasound Output Control	Clockwise rotation of this control increases, and counter-clockwise rotation decreases ultrasound output.
Ultrasound Output On Indicator	Whenever Treatment Time is started and the Ultrasound Output Control is at a zero (ccw) position, this indicator will be activated. It means that the unit is ready to deliver power by advancing the Output control clockwise. The indicator will always show a steady light in the continuous mode, whereas a pulsating light will be apparent in the Pulsed mode during the lower portions of the frequency sweep. Brightness of this pulsating light will increase or decrease with the corresponding change in pulse repetition rate. The indicator is synchronized to the pulse repetition rate and will appear as a steady light at higher pulse rates. When in the pulsed mode, this indicator will light only when the “Stimulator Output On” Indicator is on.

SECTION 4
USING THE INSTRUMENT

UltraSound Only:

1. Turn on the "Power Switch" on the front of the unit.
2. Set “Output Display Selector” to the “Ultrasound” position.
3. Set "Power/Intensity Selector” to the "Intensity" setting.
4. Set the “Stimulator Output Control” and the “Ultrasound Output Control” fully counter-clockwise.
5. Set the "Treatment Time" selector to the number of minutes for treatment (5 to 8 minutes is recommended).
6. Set "Pulsed/Continuous Selector" to “Pulsed” or “Continuous” mode as desired. Pulsed is recommended for acute conditions, continuous is recommended for chronic conditions.
7. Apply approximately 1 heaping tablespoon of coupling gel to the face of the transducer.
8. Depress the "Timer On/Off Selector" button to “On” to activate the unit.
9. Rotate the "Ultrasound Output Control" control clockwise until the desired intensity is indicated in the "Power/Intensity" display (0.50 W/cm^2 is recommended).
10. Apply the transducer to the patient and begin treatment. Keep the transducer firmly coupled and move it in circular manner at about three inches per second. Add more coupling gel as required to maintain constant, full contact between the transducer and the patient.
11. The "Ultrasound Output On" indicator shows that power is being delivered to the transducer.

The "Overtemp" indicator will light if the transducer is disconnected from the unit or overheated due to poor coupling.

Stimulator and Ultrasound Combination:

1. Turn on the "Power Switch" on the front of the unit.
2. Set “Output Display Selector” to the “Ultrasound” position.
3. Set "Power/Intensity Selector” to the "Intensity" position.
4. Set the “Stimulator Output Control” and the “Ultrasound Output Control” fully counter-clockwise (minimum setting).
5. Set the "Treatment Time" selector to the number of minutes for treatment (5 to 8 minutes is recommended).
6. Set "Pulsed/Continuous Selector" to “Pulsed” or “Continuous” mode as desired. Pulsed is recommended for acute conditions or facial treatment, continuous is recommended for chronic conditions.
7. Set the "Stimulator Polarity Selector" to “Negative”.
8. Coat the rubber pad with conducting gel or tap water, and position it on the back of the neck or the middle of the scapula. Secure the pad in place by pressure or by having the patient rest on it.
9. Apply approximately 1 heaping tablespoon of coupling gel to the face of the transducer.
12. Depress the "Timer On/Off Selector" button to “On” to activate the unit.
13. Rotate the "Ultrasound Output Control" control clockwise until the desired intensity is indicated in the "Output Display" (0.50 W/cm^2 is recommended).
14. Switch the “Output Display Selector” to the “Stimulator” setting so as to observe the applied voltage.
15. Apply the transducer to the patient and begin treatment. Keep the transducer firmly coupled and move it in circular manner at about three inches per second. Add more coupling gel as required to maintain constant, full contact between the transducer and the patient.
16. Continue with ultrasound treatment and rotate the "Stimulator Output Control" clockwise until the patient reports a slight sensation. This will occur somewhere between 30 & 100 Volts as indicated on the “Output Display”. **If no sensation is felt by the time 100 Volts is indicated, then discontinue treatment and troubleshoot the setup.**
17. Halfway through the treatment, it would be beneficial to switch the "Stimulator Polarity Selector" to “Positive” for the remainder of the treatment. This leaves the tissue in a vaso-constrictive condition.

Error Indicators

The instrument incorporates several safety features that will shut down the output power if a fault condition should arise.

Overheated Applicator:	An applicator, which is improperly coupled to the patient, will not be able to transmit energy. The ultrasonic energy will convert to heat. To prevent discomfort, circuits are included to discontinue operation should the temperature of the applicator exceed 50-60°C. This feature will also prevent damage to the applicator transducer should it be left unloaded with output power at a high level.
Defective Applicator:	If the applicator cable should open or short circuit, a fault exists. In order to protect the unit, a short circuit condition will set off a fault detector and discontinue output power. Should there be an open circuit in the applicator, the output power as shown on the indicator would drop to a low level or shut down.

If either over temperature or a Short Circuit condition occurs, the unit will shut down and notify the operator by sounding an audio alarm. The over temperature fault light will indicate for either condition. Therefore, if the applicator is not warm or hot, the fault is a short circuit. In that case, technical help must be obtained.

In the case of an overheated applicator, the unit may be used again as soon as the applicator has been allowed to cool. This may be expedited by placing the applicator in cold water for a few seconds. However, treatment time and power have to be started up again when the fault light goes off.

Safety Precautions

Qualified personnel should service this unit only. Hazardous voltage exists inside the enclosure.

CAUTION: The use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.

SECTION 5
ULTRASOUND EMISSIONS

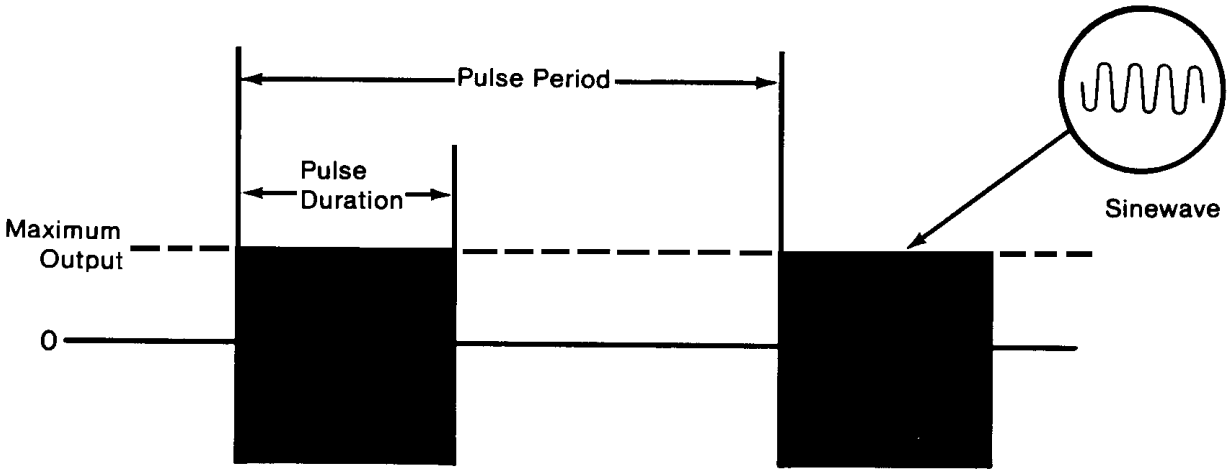
Spatial Distribution

The beam pattern of the applicator is a narrow, collimated beam when radiated into the equivalent of an infinite medium of distilled, degassed water at 30°C and with line voltage variations in the range of + or – 10% of rated value. The profile of the beam, when measured at 5 millimeters from the applicator radiating surface is cylindrical in shape with an effective radiating area of 10 square centimeters. The surface of the beam in a plane parallel to the radiating surface varies in accordance with the frequency and materials of which the applicator is constructed.

The beam pattern in all planes parallel to the applicator face also varies with distance from the radiating surface. At a distance of several inches from the applicator face, the intensity is much greater on the axis and diminishes in a bell-like manner as the distance from the axis increases. Near the applicator surface, intensity fluctuations due to phase interference occur.

Pulsed Mode Emissions

In the continuous mode, the ultrasound output is always on. The pulsed mode however, switches the power on and off. A typical waveform is shown below:



SECTION 6
TREATMENT AND CONTRAINDICATIONS

Intended Ultrasound Uses

To apply therapeutic deep heat within body tissues for the treatment of selected medical conditions such as relief of pain, muscle spasms, and joint contractures, but not for the treatment of malignancies.

Contraindications for Ultrasound use

- Over or near bone growth centers until bone growth is complete;
- Over the thoracic area if the patient is using a cardiac pacemaker
- In an area of the body where a malignancy is known to be present;
- Over a healing fracture;
- To the eye;
- Over the pregnant uterus;
- Over ischemic tissues in individuals with vascular disease where the blood supply would be unable to follow the increase in metabolic demand and tissue necrosis might result.

Precautions Regarding Ultrasound Use

- Over an area of the spinal cord following a laminectomy, i.e. when major covering tissues have been removed;
- Over anesthetic areas; and
- On patients with hemorrhagic diatheses.

Intended Stimulation Uses

Electrical stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. Indicated uses include:

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis
- Maintaining or increasing range of motion

Contraindications Regarding Stimulation Use

- Contraindicated for patients with cardiac demand pacemakers;
- Should not be used on cancer patients

Warnings Regarding Stimulator Use

- The long-term effects of chronic electrical stimulation are unknown;
- Safety has not been established for the use of electrical stimulators during pregnancy;
- Adequate precautions should be taken in the case of persons with suspected heart problems.
- Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy;
- Do not stimulate over the carotid sinus nerves, especially in patients with a known sensitivity to the carotid sinus reflex.

Precautions Regarding Stimulator Use

Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by the use of an alternate conductive medium, or alternate electrode placement.

SECTION 7
SCHEDULE OF MAINTENANCE

Ultrasound

The following schedule of maintenance is necessary to keep the *SmartSound* in compliance with applicable FDA regulations (i.e., Title 21, Part 1050.10):

The *SmartSound* should have its ultrasound output power and intensity calibrated, should have its treatment time, pulse duration and pulse period settings tested for accuracy, and should be checked for electrical safety at the place of manufacture once per year. It is important that all power calibrations be performed using distilled, degassed water with low dissolved oxygen levels. The temperature of the water should be held close to room temperature.

SoundSkin Corporation strongly recommends that all service work be performed at its manufacturing facility.

Stimulator

The pad and applicator sponges should be cleaned after each application, preferably in a Betadine solution. Sponges should not be wrapped in plastic when wet. Mold could develop when the sponges are not allowed to dry in open air. Pad sponges should be replaced periodically.

The active pads should be inspected for obvious deterioration, including the condition of the metal inserts. Metal inserts should not be kinked or split. Replace as necessary.

All cables should be inspected for wear, damage, and proper connections at the plugs. Repair or replace as necessary.

SECTION 8
LIMITED WARRANTY

Only high quality material and expert workmanship are utilized in the manufacture of all SoundSkin equipment. Any component parts, which become inoperative in normal use within two years from date of purchase will be replaced without charge. However, all shipping charges must be paid by the customer. The warranty does not apply to problems or damage resulting from misuse or mishandling.

Equipment, by definition, is considered to be the main electronic assembly and does not include any accessories.

It is usually advantageous if repairs can be made and problems eliminated in the field. Authorized SoundSkin representatives are responsible for service and repair of the equipment they sell, and they are ready to provide field service whenever such service is practical. When a problem exists, the SoundSkin dealer from whom the equipment was purchased should be contacted in order that arrangements for the service can be made.

The engineering and service specialists of the SoundSkin Corporation are always ready to be of assistance to the customer and dealer in those cases that cannot be readily solved in the field. It is often possible to resolve a problem by telephone. The factory facilities are always available when repair cannot be accomplished otherwise.

If it is necessary to return a unit to SoundSkin for repair, it will receive prompt and careful attention. The unit and accessories should be packed carefully in a strong carton or shipping case, preferably in the original carton. Shipping damage due to improper packing only results in delay and additional costs.

Mark the shipment: DELICATE ELECTRONIC EQUIPMENT - HANDLE WITH CARE

- The following information should be supplied to receive warranty service:
- Customer name and address.
- Equipment model, serial number, and date installed
- Name of dealer from whom original purchase was made.
- Nature of failure - complete description of the symptoms of the trouble (be sure to state whether the condition is present at all times or is intermittent).
- An account of steps taken in attempt to eliminate the trouble.